TURKISH JOURNAL of ORTHODONTICS

DOI: 10.4274/TurkJOrthod.2022.2021.0229

Original Article

Assessment of Changes in Craniofacial Structures, Bite Force and Periodontal Status Following Fixed Functional Appliance Therapy

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Cite this article as: Tariq M, Parakkal MS, Khan S, Khan AA. Assessment of Changes in Craniofacial Structures, Bite Force and Periodontal Status Following Fixed Functional Appliance Therapy. *Turk J Orthod.* 2023; 36(1): 22-29

Main Points
- FRD appliance was mainly associated with dentoalveolar and subsequent soft tissue changes in Class II Division 1 malocclusion patients.
- Occlusal bite force was reduced after the treatment.
- There was increased plaque formation, gingival bleeding, probing pocket depth with Forsus appliance without any change in clinical attachment levels.

ABSTRACT

Objective: The aim of this study was to determine the effect of Forsus Fatigue Resistant Device (FRD) appliance on craniofacial structures, bite force and periodontal status in Class II malocclusion patients.

Methods: In this prospective interventional follow-up study, thirteen (13) Class II Division 1 patients in their post-adolescent age group with average age of 17.10 ± 1.63 year was treated with Forsus FRD. They were assessed for craniofacial changes, bite force and periodontal status at baseline, after alignment and leveling, after removal of FRD.

Results: Improvement in soft tissue profile was due to significant dentoalveolar changes. There were significant decreases in overjet, overbite, reference line to upper first molar, H angle ($p<0.001$) and significant increases in upper lip to E-line, reference line to lower molar and angular measurements like nasolabial angle, U1 to SN plane, Incisor Mandibular Plane Angle ($p<0.001$). The bite force was significantly decreased on the molar and the incisor region ($p<0.001$). A significant increase in plaque index (PI), gingival index (GI), probing pocket depth was noticed without any significant clinical attachment loss.

Conclusion: Class II correction with Forsus FRD appliance was mainly due to significant dentoalveolar changes. Skeletal changes were non-significant. A decrease in the bite force was found with FRD. The magnitude of bite force was more in males compared with females. The increase in GI, PI, pocket probing depth implies the necessity of oral hygiene and plaque control measures. However, there was no significant change in clinical attachment level.

Keywords: Forsus FRD, fixed functional appliance, bite force, Class II Division I malocclusion, plaque index, gingival index

INTRODUCTION

Class II malocclusion is the most frequent problem encountered in orthodontics after crowding. This problem adversely affects the facial aesthetics and functional status.[1] The most common characteristic of Class II malocclusion is mandibular retrognathia rather than maxillary protrusion.[2] The treatment includes growth modification in growing patients. In contemporary orthodontics, an unparalleled number of options are available for correcting this malocclusion for an orthodontist.[3] Selection of the appliance also depends on the

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Received: November 12, 2021
Accepted: June 13, 2022
Epub: March 10, 2023
Publication Date: March 21, 2023

growth status of the patient. More skeletal effects have been achieved in adolescent patients than in the post adolescent age group when Twin-block appliance was compared with Mandibular Protraction Appliance (MPA-IV).[4] But Twin-block requires more patient compliance. One of the effective Class II correction device in post-adolescent age group causing more dentoalveolar effect is the Forsus Fatigue Resistant Device (FRD), a compliance free appliance that was developed to overcome breakage problems seen with the Jasper Jumper.[5,6] Forsus FRD applies a constant light force of approximately 200 grams and this device effectively eliminates the use of a long headgear treatment.

Occlusal bite force (OBF) is a key predictor for masticatory performance and it can provide useful data for evaluation of jaw muscle function, muscle activity and as an adjunctive aid in assessing the performance of dentition. Moreover, patients wearing fixed appliances were seen to have more pressure, tension, pain, and sensitivity of teeth. Changes in the activity of elevator muscles and occlusal disturbances during orthodontic treatment are likely to disturb the OBF. Bite force was shown to decrease with the use of Andresen functional appliance and fixed orthodontic treatment.[7,8] FRD also produces dentoalveolar changes; however, the effect of Forsus FRD appliance on the bite force and periodontal health remains unclear.

Thus, it was pertinent to evaluate the effect of Forsus FRD appliance on the bite force and its effect on the periodontal status in the patients undergoing orthodontic treatment. Considering the above evidence, we hypothesize that the use of Forsus FRD appliance will result in a decrease in bite force and will compromise the periodontal health in subjects undergoing fixed functional mechanotherapy. Therefore, the present study measured changes in the craniofacial structures, OBF and periodontal status in the patients undergoing fixed functional appliance treatment with Forsus FRD appliance.

METHODS

A prospective interventional follow-up study was conducted in the Department of Orthodontics and Dentofacial Orthopedics in collaboration with Departments of Periodontics and Mechanical Engineering of Aligarh Muslim University. Subjects included were post adolescent individuals with Class II Division 1 malocclusion and positive VTO. After leveling and alignment, Forsus FRD (L-pin Spring Module, 3M Unitek, Monrovia, Calif, USA) was used as the treatment plan. The average duration of the Forsus FRD was 5.5 months. The study was approved by the Institutional Ethical Committee of Aligarh Muslim University in accordance with the declaration of Helsinki 1964, including 2013 amendments (1029/FM dated 13/07/2018). The subjects who agreed to participate and signed the patient consent form and who fulfilled the following criteria were included in the study.

Inclusion Criteria:

- Age between 14 - 20 years
- Class II Division 1 malocclusion with positive VTO
- Cervical vertebrae maturation index (CVMI) between stages III and V
- Overjet >5 mm and crowding of <5 mm

Exclusion Criteria:

- Patients having posterior crossbite
- Signs and symptoms of TMD
- Craniofacial anomalies and systemic muscle or joint disorders
- Periodontal disease

Taking the power of study (β) 80%, the required sample size in the interventional group was calculated by the formula $n=2\ SD^2\ (Z\alpha/2 + Z\beta)^2\ /d^2$, where SD (standard deviation) of the bite force in a previous study[9] is 72.6 N and effect size or difference (d) in the bite force after the functional appliance is 40 N. The value of Zα/2 is 1.96 and Zβ is 0.842 at type 1 or alpha error of 5%. The required sample size in the intervention arm is 13 subjects.

Out of 250 patients examined for the study from 01/08/2018 to 15/02/2019, 199 subjects did not meet the criteria. Out of 51 subjects who met the selection criteria, 27 declined to participate and 11 did not turn up on appointment. Thus 13 subjects having Class II Division 1 malocclusion with positive VTO were included in the study comprising 6 males and 7 females with an average age of 17.10 ± 1.63 years, using Forsus FRD appliance as a treatment plan. Figures 1 and 2 show a CONSORT flow chart of the clinical study and attachment of Forsus FRD after leveling and alignment.

All the 13 recruited subjects underwent full mouth oral prophylaxis followed by comprehensive oral hygiene instructions The patients were instructed to brush with a horizontal technique and using interdental brush.

All the selected subjects were bonded with MBT Prescription pre-adjusted edgewise bracket with 0.022x0.028 inch slots in both the arches and were aligned with the sequence of NiTi wires and Forsus FRD was delivered after reaching a heavy stainless steel wire of 0.019x0.025 inch. Data were collected at the following time points;

T1: Before treatment

T2: After leveling

T3: After the removal of the Forsus appliance

Craniofacial assessment was performed on the digital lateral head cephalogram manual tracings. Cephalogram of each subject were obtained by orienting them in the natural head position. 23 cephalometric parameters (8 skeletal, 5 soft tissue, 10 dentoalveolar) were measured. Figure 3 shows various craniofacial parameters.

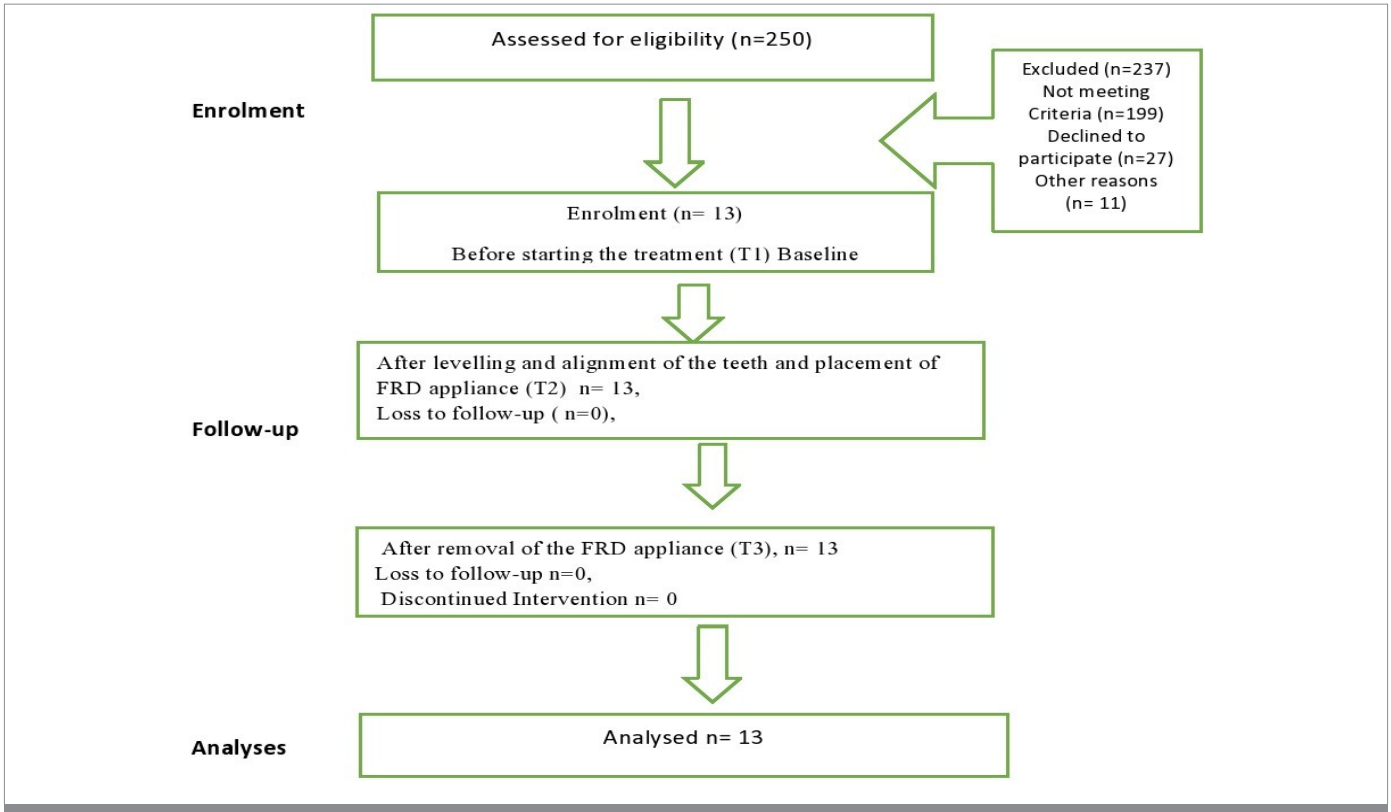


Figure 1. Showing the CONSORT flow of the clinical study

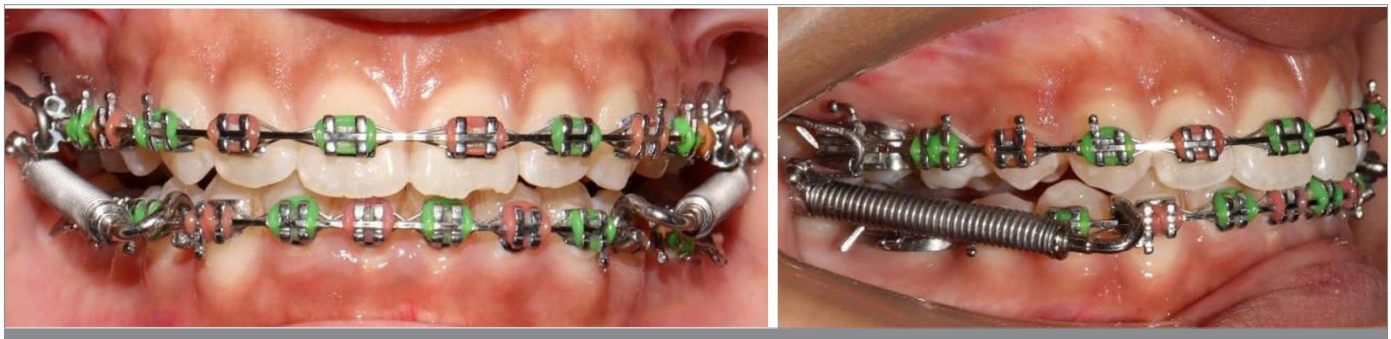


Figure 2. Attachment of Forsus FRD after leveling and alignment
FRD, Fatigue resistant device.

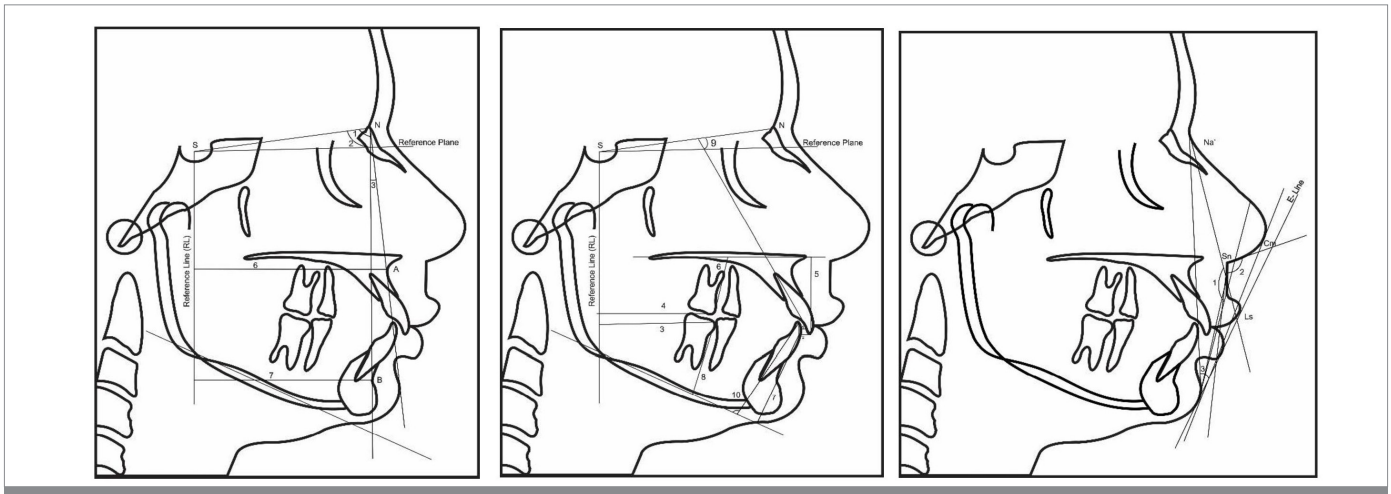


Figure 3. Lateral cephalogram tracing shows skeletal, dentoalveolar and soft tissue variables

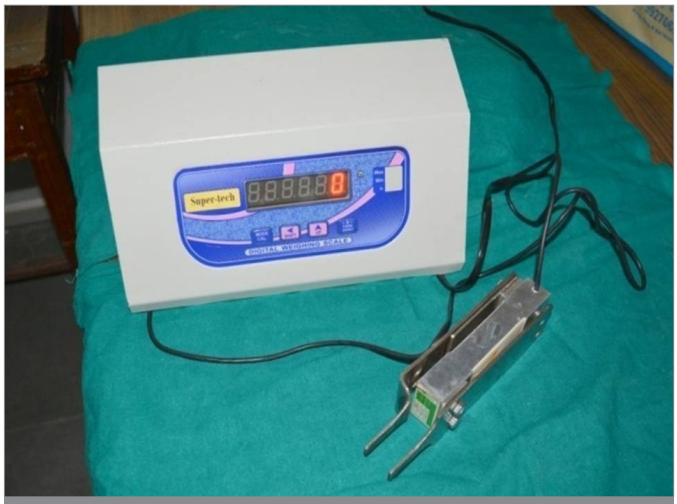


Figure 4. Bite force measuring device

Skeletal Variables:

1. SNA, 2. SNB, 3. ANB, 4. Sella Nasion-Mandibular Plane (SN-MP), 5. SN-Palatal Plane, 6. Reference Line to A point (RL-A), 7. Reference Line to B point (RL-B), 8. Jarabak Ratio.

Dentoalveolar Variables:

1. Overjet, 2. Overbite, 3. RL-Lower first molar (M1) (mm), 4. RL-Upper M1 (mm), 5. Upper incisor to the nasal floor (NF) (mm), 6. Upper M1 to the NF (mm), 7. Lower incisor to the mandibular plane (mm), 8. Lower M1 to the mandibular plane (mm), 9. Upper incisor to SN plane (degree), 10. Incisor Mandibular Plane Angle (IMPA).

Soft Tissue Variables :

1. Angle of soft tissue convexity (Na'-A'-Pog'), 2. Nasolabial angle, 3. H- Angle (Na'-Pog'-Tangent to upper lip), 4. Upper Lip-E line, 5. Lower Lip-E line.

Maximum voluntary OBF was recorded using a custom-fabricated device in which a strain gauge load cell was connected to a digital display having a precision of 1 gram. Figure 4 shows bite force measuring device.

All the subject's bite force was measured at the 3 stages of treatment T1, T2, and T3. OBF was recorded at the incisal and first permanent molar region on both right and left sides. Before recording, each subject was instructed to sit upright, looking forward without head support and with the Frankfort plane parallel to the floor. OBF was recorded three times at each side and the incisal region with a 20-second rest between each bite and the average of the reading was taken and compared.

Baseline periodontal parameters; plaque index (PI by Silness and Loe[9], gingival index (GI) by Loe and Silness[10], probing Pocket depth and clinical attachment level (CAL) were evaluated before starting the orthodontic treatment to ensure a non-inflammatory environment for the treatment and none of the patients had clear gingival or periodontal disease initially. Oral prophylaxis was performed in every subject before treatment and after the leveling and alignment of teeth. PI, GI, PPD, CAL at the mandibular incisors and first maxillary molars were considered for periodontal evaluation using University of North Carolina-15 periodontal probe (UNC-15). (Hu-friedy PCPUNC 156, 0417, USA).

Statistical Analysis

Statistical analysis was performed with Statistical Package for Social Sciences (SPSS) software (IBM Corp, Armonk, NY, USA). Descriptive statistics were applied for the mean and standard deviation for each variable. To analyze the changes seen between two stages of the treatment, Paired t-test was used for normally distributed data and the Wilcoxon signed-rank test was used for variables which were not normally distributed. Changes were analyzed between T1-T2, T2-T3, and overall change of treatment as T1-T3 (Table 1). The correlation was checked between bite force and periodontal variables with the Pearson correlation test.

RESULTS

Non-significant changes were found after treatment with FRD appliance in skeletal craniofacial angular measurements (SNA, SNB, ANB and SN-PP angles) and linear measurements (RL-A, RL-B in mm) when compared T1-T2, and after the use of FRD appliance (when compared between T2-T3). Significant changes were found only in SN-MP angle with the increase of 1.69° (when compared between T1-T3) ($p<0.001$) (Table 2).

Upper lip to E line distance showed a significant increase of 0.73 mm and a decrease of 2.53° in H angle with Forsus FRD appliance between T2-T3, ($p<0.01$, $p<0.001$), between T1-T3 ($p<0.001$) ($p<0.01$) (Tables 2, 3). Although changes in the nasolabial angle were non-significant with FRD appliance between T2- T3, it showed a significant increase between T1-T3 ($p<0.05$) (Table 2). Non-significant changes were seen in the lower lip.

With Forsus FRD appliance, overjet and overbite had showed significant improvement between T1-T2, T2-T3, and T1-T3 ($p<0.001$) (Tables 2). Upper Incisor - SN Plane significantly increased ($p<0.001$) with the use of Forsus FRD. Lower incisor showed a proclination of 7° with Forsus when compared T2-T3 and 9.53° during T1-T3 ($p<0.001$). IMPA was significantly increased during period T1-T2, T2-T3, and T1-T3, ($p<0.01$), ($p<0.001$), ($p<0.001$) respectively. The distance of the upper M1 from the RL and from the NF was significantly decreased when compared T2- T3, T1-T3 ($p<0.001$), ($p<0.001$) respectively and distance of lower M1 from the RL was significantly increased during T2-T3 ($p<0.001$) (Table 2).

The bite force significantly decreased during leveling and alignment (T1-T2), this decrease in bite force was 22.29 N, 36.12 N, and 35.19 N at the incisor, right molar, and left molar regions, respectively ($p<0.001$). Similarly, bite force showed significant decreases of 13.83 N, 33.39 N, and, 32.47 N at the incisor, right molar and left molar regions, respectively, when Forsus FRD was used (T2-T3) ($p<0.001$). During (T1-T3) the net decrease in bite

Table 1. Descriptive statistics with mean and standard deviation of all the variables taken for the study at T1, T2 & T3

Skeletal Variables	T1	T2	T3
	Mean±SD	Mean±SD	Mean±SD
SNA (°)	80.92 ± 3.33	81.00 ± 3.29	80.85 ± 3.21
SNB (°)	75.30 ± 3.59	75.46 ± 3.55	75.69 ± 3.68
ANB (°)	5.61 ± 1.93	5.54 ± 1.94	5.15 ± 1.57
SN-MP angle (°)	32.15 ± 6.76	32.69 ± 6.99	33.84 ± 6.82
SN-palatal plane (PP) angle (°)	7.92 ± 2.87	8.38 ± 3.01	8.46 ± 2.96
Reference line-A point (mm)	67.91 ± 5.94	68.13 ± 5.39	67.81 ± 5.36
Reference line-B point (mm)	59.25 ± 6.37	59.72 ± 6.29	60.08 ± 6.17
Jarabak ratio (%)	68.53 ± 7.01	67.53 ± 7.25	66.36 ± 7.18
Soft Tissue Variables			
Angle of soft tissue convexity (°)	25.38 ± 5.32	24.23 ± 4.68	22.31 ± 4.01
H angle (°)	21.23 ± 3.63	20.30 ± 3.28	17.76 ± 3.16
Nasolabial angle (°)	102.08 ± 8.89	103.38 ± 9.19	105.38 ± 8.02
Upper lip-E line (mm)	-0.96 ± 1.82	-1.42 ± 1.51	-2.19 ± 1.71
Lower lip-E line (mm)	-2.04 ± 3.50	-1.54 ± 3.22	-1.22 ± 2.81
Dentoalveolar Variables			
Overjet (mm)	9.44 ± 2.37	6.61 ± 1.16	2.46 ± 0.59
Overbite (mm)	6.38 ± 1.94	4.05 ± 1.59	1.96 ± 0.78
Upper incisor-SN plane (°)	61.15 ± 8.42	61.69 ± 6.92	66.30 ± 7.12
Upper incisor-nasal floor (mm)	25.50 ± 3.33	25.78 ± 3.26	26.25 ± 3.34
Upper molar-nasal floor (mm)	20.90 ± 1.68	21.90 ± 1.69	20.42 ± 1.52
Lower incisor-mandibular plane (mm)	44.03 ± 2.89	42.89 ± 2.55	40.21 ± 2.31
Lower molar-mandibular plane (mm)	31.05 ± 3.20	31.83 ± 2.92	32.09 ± 2.44
Reference line-upper molar (mm)	42.24 ± 1.06	42.16 ± 1.11	40.35 ± 1.01
Reference line-lower molar (mm)	38.90 ± 1.33	39.02 ± 1.36	42.83 ± 0.91
IMPA (°)	95.92 ± 8.86	98.46 ± 6.75	105.46 ± 6.86
Bite Force Variables			
Bite force at incisor	62.18 ± 12.9	39.88 ± 8.66	26.04 ± 6.32
Bite force at right molar	124.28 ± 22.29	88.16 ± 16.67	54.77 ± 10.92
Bite force at left molar	124.05 ± 20.06	88.46 ± 15.8	55.99 ± 12.77
Periodontal variables			
Plaque index (PI)	0.78 ± 0.10	1.15 ± 0.14	1.44 ± 0.19
Gingival index (GI)	0.17 ± 0.03	0.38 ± 0.11	0.58 ± 0.11
Probing depth at lower anteriors	1.93 ± 0.09	2.11 ± 0.15	2.30 ± 0.17
Probing depth at upper molar	2.15 ± 0.15	2.71 ± 0.14	2.85 ± 0.12
Clinical attachment level at lower anteriors	0.64 ± 0.16	0.66 ± 0.17	0.67 ± 0.17
Clinical attachment level at upper molar	0.51 ± 0.21	0.53 ± 0.17	0.57 ± 0.16

IMPA, Incisor Mandibular Plane Angle; SN-MP, Sella Nasion-Mandibular Plane

force was 36.13 N, 69.15 N and 68.06 N at incisor, right molar, and left molar regions, respectively and it was significant (p<0.001). It was 58 percent of pre-treatment value at the incisor region, and 55 percent at molar region (Table 2).

Although the bite force significantly decreased at different time intervals when compared between males and females on the right and left M1s in males it was significantly high at different time intervals [T1 (p<0.01), (p<0.05) at T2, (p<0.01), (p<0.05) at T3 (p<0.05). (p<0.05)] respectively. In males the magnitude of bite force was significantly greater than the females at M1 region (p<0.001), (Table 4).

PI and GI showed significant increases during the leveling and alignment phases and in the Forsus FRD treatment phase. PI and GI showed an increase of 0.36 and 0.21 during T1-T2 and 0.29 and 0.21 during T2-T3 respectively. The average probing depth at the anterior and molar regions had showed statistically significant increase of 0.17 mm and 0.14 mm, respectively, during TI-T2 and 0.18 mm and 0.14 mm during the time Forsus FRD. The CAL had showed no significant change at the anterior and molar region (Table 2).

Table 2. Difference in mean of variables between pretreatment and after leveling (T1-T2), before and after removal of Forsus FRD (T2-T3), and before treatment and after removal of Forsus FRD (T1-T3)

	T1-T2			T2-T3			T1-T3		
Skeletal variables	**Mean**	**SE**	**p value**	**Mean**	**SE**	**p value**	**Mean**	**SE**	**p value**
SNA (⁰)	0.07	0.07	0.33	-0.15	0.05	0.33	-0.08	0.12	0.95
SNB (⁰)	0.15	0.40	0.16	0.23	0.17	0.19	0.38	0.21	0.09
ANB (⁰)	-0.07	0.07	0.33	-0.38	0.20	0.13	-0.46	0.69	0.11
SN-MP angle (⁰)	0.53	0.18	0.10	1.15	0.19	0.454	1.69	0.26	0.001*
SN-palatal plane angle (⁰)	0.46	0.26	0.11	0.07	0.13	0.58	0.54	0.11	0.64
Reference line - A Point (mm)	0.22	0.32	0.50	-0.32	0.19	0.129	-0.10	0.22	0.96
Reference line - B Point (mm)	0.46	0.12	0.08	0.36	0.09	0.778	0.82	0.14	0.66
Jarabak ratio (%)	-1.00	0.21	0.72	-1.16	0.10	0.329	-2.17	0.27	0.44
Soft tissue variables									
Angle of soft tissue convexity	-1.15	0.51	0.56	-1.92	0.31	0.216	-3.08	0.18	0.11
H angle	-0.92	0.28	0.21	-2.53	0.24	0.001*	-3.46	0.44	0.01*
Nasolabial angle	1.30	0.79	0.13	2.00	0.96	0.06	3.30	0.34	0.03*
Upper lip - E line (mm)	-0.46	0.23	0.07	-0.76	0.23	0.007*	-1.23	0.68	0.001*
Lower lip - E line (mm)	0.50	1.32	0.13	0.32	0.33	0.38	0.82	0.12	0.52
Dentoalveolar variables									
Overjet (mm)	-2.00	0.32	<0.001*	-4.15	0.28	<0.001*	-6.15	0.70	<0.001*
Overbite (mm)	-2.33	0.70	<0.001*	-2.09	0.39	0.001*	-4.42	0.58	<0.001*
Upper incisor - SN plane (⁰)	1.30	0.81	0.13	4.61	0.18	0.001*	5.92	0.30	<0.001*
Upper incisor - Nasal floor (mm)	0.27	0.32	0.41	0.47	0.23	0.06	0.75	0.13	0.57
Upper molar - Nasal floor (mm)	1.00	0.21	<0.001*	-1.47	0.12	0.003*	-0.48	0.63	0.46
Lower incisor - Mandibular plane (mm)	-1.13	0.31	0.004*	-2.58	0.42	0.001*	-3.82	0.11	<0.001*
Lower molar - Mandibular plane (mm)	0.77	0.23	0.006*	0.26	0.31	0.42	1.04	0.11	0.36
Reference line - Upper molar (mm)	-0.08	0.42	0.84	-1.80	0.22	<0.001*	-1.89	0.41	<0.001*
Reference line - Lower molar (mm)+	0.11	0.52	0.82	3.82	0.19	<0.001*	3.93	0.44	<0.001*
IMPA (⁰)	2.53	0.88	0.04*	7.00	0.27	<0.001*	9.53	0.87	<0.001*
Bite force									
Bite force at incisor	-22.29	1.79	<0.001*	-13.83	1.44	<0.001*	-36.13	2.6	<0.001*
Bite force at right molar	-36.12	2.93	<0.001*	-33.39	2.47	<0.001*	-69.15	4.3	<0.001*
Bite force at left molar	-35.59	2.53	<0.001*	-32.47	2.41	<0.001*	-68.06	3.8	<0.001*
Periodontal variables									
Plaque index	0.36	0.02	<0.001*	0.29	0.03	<0.001*	0.66	0.06	<0.001*
Gingival index	0.21	0.03	<0.001*	0.21	0.03	<0.001*	0.42	0.03	<0.001*
Probing depth at lower anteriors	0.17	0.05	<0.001*	0.18	0.02	<0.001*	0.37	0.05	<0.001*
Probing depth at upper molar	0.55	0.06	<0.001*	0.14	0.07	0.013*	0.70	0.05	<0.001*
Clinical attachment level at lower anteriors	0.02	0.04	0.65	0.01	0.02	0.608	0.03	0.06	0.61
Clinical attachment level at upper molar	0.02	0.11	0.43	0.03	0.01	0.117	0.06	0.07	0.43

*p<0.05 significant, Paired t-test & Wilcoxon signed-rank test, SN-MP, Sella nasion-Mandibular plane; IMPA, Incisor mandibular plane angle; SE, Standard error

Table 3. Comparison of mean of maximum bite force on right molar and left molar region at T1, T2 & T3

	Right molar (Newton)	Left molar (Newton)	p value
	Mean ± SD	**Mean ± SD**	
Before treatment (T1)	124.28 ± 22.29	124.05 ± 20.06	0.979
After leveling (T2)	88.16 ± 16.67	88.46 ± 15.8	0.963
After removal of Forsus FRD appliance (T3)	54.77 ± 10.92	55.99 ± 12.77	0.795

*p<0.05 significant, Unpaired t-test
FRD, Fatigue Resistant Device

Table 4. Comparison of maximum occlusal bite force in male and female at T1, T2 & T3

		Male	Female	Mean difference	p value
		Mean ± SD	Mean ± SD		
Bite force at incisor	T1	69.32±10.52	56.05±10.58	13.26	0.063
	T2	43.86±9.33	36.47±5.26	7.38	0.157
	T3	27.07±4.98	25.16±6.45	1.90	0.603
Bite force at right molar	T1	140.28±14.25	110.57±16.33	29.71	0.008*
	T2	101.90±10.99	76.37±8.31	25.53	0.002*
	T3	61.41±10.01	49.07±6.87	12.33	0.046*
Bite force at left molar	T1	137.99±11.32	112.11±16.47	25.87	0.011*
	T2	99.62±9.54	78.90±12.32	20.72	0.010*
	T3	64.09±10.85	49.05±8.54	15.04	0.033*

*p<0.05 Significant, Unpaired t-test

DISCUSSION

Our study showed that Class II correction achieved with Forsus FRD appliance in post-adolescent age group patients was mainly by maxillary and mandibular dentoalveolar changes without any skeletal changes. Similar findings were reported by Gunay et al.[11] with Forsus FRD and other study reported by Eissa et al.[12] with miniscrew-anchored Forsus FRD. Interestingly, Mahamad et al.[13] showed more skeletal changes with Twin Block appliance as compared to Forsus FRD appliance in growing patients. In a similar recent study, Kalra et al.[14] used Power scope- a fixed functional appliance and found significant skeletal dental and soft tissue changes. Also, Badri[15] in his study reported a mandibular unlocking effect and effective Class II correction with Class II elastics.

We found improvement in the soft tissue facial profile that was associated with upper and lower lip fall due to retroclination of the upper incisors and proclination of lower incisors and reduction in overjet. Similar soft tissue changes were reported by Stromeyer et al.[16] and by Nalbantgil et al.[17] with Eureka spring and Jasper Jumper, respectively.

The overbite also improved due to intrusion and proclination of lower incisors due to an intrusive force vector of Forsus FRD on the lower anterior region and extrusion of mandibular posteriors. Retroclination of maxillary incisors and distalization and intrusion of maxillary molars were considerably noticed due to high pull effect of the appliance since the attachment of Forsus gives a force vector directed both backward and upward on the maxillary molars. It is also below and behind the centre of resistance of maxillary dentition. This finding was consistent with studies using Forsus Nitinol Flat Spring and Jasper Jumper.[18,19] Class-II correction of 5.62 mm was achieved with the use of Forsus FRD in which 68% of molar correction was achieved by mesialization of the mandibular molars and 32% was by distalization of the maxillary molars.

In our study with Forsus FRD appliance, bite force decreased during the leveling and alignment phases and the active treatment phase. Similar findings were reported previously by Therkildsen and Sonnesen[8] and Alomari and Alhaija[20] with fixed orthodontic treatment and they reported a significant decrease in occlusal contact during treatment but it reached the pre-treatment level at post retention. Al-Khateeb et al.[7] in their study with Andresen functional appliance treatment also showed a significant reduction in OBF immediately after treatment. Researchers have reported neuromuscular and skeletal adaptations following mandibular forward positioning induced by the Herbst appliance.[21] A reduction in OBF during the fixed functional appliance can be attributed to changes in masticatory muscle activity.

Functional appliance treatment may directly affect the functional pattern of masticatory muscles.[22] Although these elevator muscles have a good range of adaptation to systemic and local environmental changes, changes in the functional pattern of these muscles cause changes in activity and thereby a reduction in bite force.[23] This study also showed that males have a higher bite force reading than females at the stages and can be attributed to males having larger teeth size and correspondingly greater periodontal area and due to increased activity of masticatory muscles.

Increased plaque accumulation and subsequent inflammation of gingiva were seen during the treatment because of its buccally placed assembly, which makes performing oral hygiene measures more difficult for the patients. There was an increase in the probing pocket depth because of pseudopocket formation due to hyperplasia of gingival tissue or marginal gingivitis, which is usually seen during the fixed orthodontic treatment however there was no change in CAL. So this study reveals that the use of a fixed functional appliance like Forsus FRD does not cause any destructive changes in the periodontium even though it causes gingival inflammation, which is always associated with fixed orthodontic treatment. No available literature to date shows that functional appliance, either fixed or removable causes irreversible change in periodontal structures hence fixed functional appliance like Forsus FRD can be used with proper oral hygiene in periodontally healthy individuals. In periodontally compromised cases in the presence of an active inflammatory condition, the use of fixed functional appliances should be avoided.

The novelty of this study is that it specifically measured the effect of Forsus FRD therapy on the OBF and periodontal status for the first time.

Study Limitations

Since patients applied maximum OBF from a stretched position rather than biting from a relaxed condition of masticatory muscle, the maximum OBF measured in this study was lower than that of the optimal range. Also, the follow-up readings of the occlusal force were not taken after the completion of the treatment.

CONCLUSION

The Forsus FRD appliance was effective in treating Class II malocclusion mainly due to the significant dentoalveolar changes without any significant skeletal changes in post adolescent individuals. Improvement in the soft tissue profile of the patients was owed to the dentoalveolar changes because the lip followed changes in incisor position. The maximum OBF was decreased during the leveling and alignment phases and during the active treatment with Forsus FRD and the OBF value was seen to be higher in males than in females. Increased plaque accumulation and subsequent increase in gingival inflammation were noticed during the treatment, but there was no loss of periodontal attachment with the use of Forsus FRD appliance.

Ethics

Ethics Committee Approval: The study was approved by the Institutional Ethical Committee of Aligarh Muslim University in accordance with the declaration of Helsinki 1964, including 2013 amendments (1029/FM dated 13/07/2018).

Informed Consent: Informed consent was obtained.

Peer-review: Internally and externally peer-reviewed.

Author Contributions: Author Contributions: Concept - M.T., M.S.P., S.K., A.A.K.; Design - M.T., M.S.P., S.K., A.A.K.; Data Collection and/or Processing - M.T., M.S.P., S.K., A.A.K.; Analysis and/or Interpretation - M.T., M.S.P., S.K., A.A.K.; Literature Review - M.T., M.S.P., S.K., A.A.K.; Writing - M.T., M.S.P., S.K., A.A.K.

Declaration of Interests: The authors have no conflicts of interest to declare.

Funding: The authors declared that this study has received no financial support.

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